

**REMARKS**

Entry of the foregoing, re-examination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Claims 7-9 , 14-15, 38, 50-63 and 90-103 are under examination.

Claims 7-9, 11 and 13 have been allowed.

The Examiner has rejected claims 14-15, 38, 50-63 and 90-103 under 35 U.S.C. § 112, first paragraph, as not enabled. This rejection is respectfully traversed. Further, Applicants believe that claim 38 is incorrectly included in this group.

The Examiner has asserted that while Applicants have enabled the treatment of anaphylactic reactions with the peptide FEG, the specification does not enable such treatments with a peptide of the formula  $R_1-X_1-X_2-R_2$  as defined in the claims.

Applicants argued in their last response that they have demonstrated the efficacy of a sufficient number of peptides to enable the claims without undue experimentation being required to practice the invention, as shown in the Tables contained in the specification as filed.

The Examiner now argues, in the Official Action of February 11, 2002, that Table 2 demonstrates that of ten peptides tested, six peptides showed no activity and only three showed activity greater than 40%.

It is respectfully submitted that the Examiner's characterization of the data of Table 2 is incorrect.

Table 2 shows that peptides TDIFEGG, TAIFEGG, TDAFEGG, FEGGG and FEG, all of which fall within the general formula  $R^1-X^1-X^2-R^2$  as defined in claims 14 and 15, showed activity in inhibiting antigen-induced intestinal contraction. Peptide TDIFAGG (SEQ ID No: 6), which also falls within that general formula, appeared in the experiment reported in Table 2 to be inactive but that appears to have been an experimental anomaly in that one experiment as this peptide is active, as shown in Table 3 and subsequently confirmed.

The remaining five peptides of Table 2, STDIFEGG, ADIFEGG, TDIAEGG, TDIFEGG-NH<sub>2</sub> and TDIFE, do not fall within the general formula  $R^1-X^1-X^2-R^2$  as defined in claims 14 and 15.

Therefore, of the eleven peptides tested in Table 2, six fall within the formula of the claims and five do not. Of the six peptides within the formula of the claims, all have been shown to have activity. None of the five peptides which do not fall within the formula showed activity.

The examples in the specification are, therefore, not "[e]xamples where the majority of peptides were inactive" as suggested by the Examiner.

Furthermore, the mere fact that a claim embraces inoperative species or embodiments does not necessarily render it unduly broad. *See, e.g., Atlas Power Co. v. E.I. DuPont de Nemours & Co.*, 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984); *Horton v. Stevens*, 7 U.S.P.Q.2d 1245, 1247 (PTO Bd. App. & Int. 1988). It is not the function of the claims to specifically exclude possible inoperative substances. *See, e.g., Atlas Power*,

224 U.S.P.Q. at 414; *Ex Parte Hradcovsky*, 214 U.S.P.Q. 554, 556 (PTO Bd. App. 1982).

To expedite prosecution in the subject application, and not to acquiesce to the Examiner's rejection, claims 14, 15 and 25 have been amended to remove references to "preventing" anaphylactic reactions.

In view of the above, the Examiner is respectfully requested to reconsider his position and conclude that the claims are adequately enabled with respect to treating anaphylactic reactions with the peptides of the formula of claims 14 and 15.

Additionally, claims 92 and 93 have been amended and claims 104 and 105 have been added to relate to more limited groups of peptides than claims 14 and 15.

Withdrawal of the enablement rejection under 35 U.S.C. § 112, first paragraph, is thus respectfully requested.

The Examiner has also rejected claims 90 and 91 under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

To expedite prosecution in the subject application, and not to acquiesce to the Examiner's rejection, claims 90 and 91 have been canceled without prejudice or disclaimer to the subject matter recited therein.

It is noted for the record that claim 95 has been amended to correct an unintended error.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this Amendment and Reply, or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:

  
Susan M. Dadio

Registration No. 40,373

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

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**Mark-up of Claims**

14. (Amended) A method for treating [or preventing] anaphylactic hypotension in a mammal comprising administering to the mammal an effective amount of a peptide of the formula:  $R^1 - X^1 - X^2 - R^2$

wherein  $X^1$  is an aromatic amino acid residue;

$X^2$  is any amino acid residue; and

$R^1$  is  $NH_2$ - or an amino acid sequence  $X^3 - X^4 - X^5$

wherein  $X^3$  is an aliphatic amino acid residue having a side chain hydroxyl group and  $X^4$  and  $X^5$  are the same or different and are any amino acid residue and wherein  $R^2$  is 1 to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide.

15. (Amended) A method of reducing [or preventing] an anaphylactic reaction in a mammal comprising administering an effective amount of a peptide of the formula:

$R^1 - X^1 - X^2 - R^2$

wherein  $X^1$  is an aromatic amino acid residue;

$X^2$  is any amino acid residue; and

$R^1$  is  $NH_2$ - or an amino acid sequence  $X^3 - X^4 - X^5$

wherein  $X^3$  is an aliphatic amino acid residue having a side chain hydroxyl group and  $X^4$  and  $X^5$  are the same or different and are any amino acid residue and wherein  $R^2$  is 1

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to 3 amino acid residues which are the same or different and are aliphatic amino acid residues or of an effective fragment or derivative of said peptide to the mammal.

25. (Amended) A method for treating [or preventing] systemic inflammatory response syndrome (SIRS) in a mammal comprising administering to the mammal an effective amount of the peptide of claim 11 of an effective fragment or derivative of said peptide.

92. (Amended) The method of claim 14 wherein

X<sup>1</sup> is an aromatic amino acid residue;

X<sup>2</sup> is [any] an acidic amino acid residue;

R<sup>1</sup> is NH<sub>2</sub>- and

R<sup>2</sup> is a single aliphatic amino acid residue.

93. (Amended) The method of claim 15 wherein

X<sup>1</sup> is an aromatic amino acid residue;

X<sup>2</sup> is [any] an acidic amino acid residue;

R<sup>1</sup> is NH<sub>2</sub>- and

R<sup>2</sup> is a single aliphatic amino acid residue.

95. (Amended) The method of claim 15 wherein

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X<sup>1</sup> is phenyl alanine [an aromatic amino acid residue;

X<sup>2</sup> is any amino acid residue];

R<sup>1</sup> is NH<sub>2</sub>- and

R<sup>2</sup> is a single aliphatic amino acid residue.